

EPA Registration Jacket 72642-10

Vol. 2

PROCESSING REQUEST

Reg # 72642-10 Decision # 505398

Description:

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated:

May 11, 2015

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Olga Odiott

Division: RD

Phone: 703-308-9369

Date: 6/3/2015



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 3, 2015

Casey Ash
Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140

Subject: CSF Notification per PRN 98-10 – Revise Basic CSF: Replace Production Site
Product Name: Cheristin for Cats
EPA Registration Number: 72642-10
Application Date: May 11, 2015
Decision Number: 505398

Dear Ms Ash:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated May 11, 2015

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Olga Odiott by phone at 703-308-9369, or via email at odiott.olga@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Walsh", is written over a horizontal line.

Michael Walsh, Product Manager 11
Vertebrate & Invertebrate Branch 2
Registration Division (7505P)
Office of Pesticide Programs

Receipt for Section 3

S: 968404 Milestone Email: _____

Regulatory Type: Product Registration - Section 3 Resubmission: ☐ Yes ☒ No

Application Type: Notification Fee For Service: ☐ Yes ☒ No

Company: 72642 ELANCO ANIMAL HEALTH

Risk Manager: Registration Division, Risk Management Team 11

Product #: 72642-10 Product Name: CHERISTIN FOR CATS

Override#: _____

Me Too Section3: 72642-9 Me Too Product Name: ASSURITY CAT

Application Date: 11-May-2015 OPP Rec'd Date: 13-May-2015

Front End Date: 13-May-2015 Risk Manager Send Date: 13-May-2015

FFS Due Date: _____ Negotiated Due Date: _____

OPP Target Date: _____

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

CSF Notification to revise basic formulation by updating the production site

Form A: ☐ Signature Date: _____ Form B: ☐ Signature Date: _____

Receipt Content	Des
CSF	

On for end use product
High for tech products
10/11/15
Group 1 data - See 158. 700

Cons. w/
Pence letter
6/3/15

332
Olga

MAY 14 2015



Elanco Animal Health

2500 Innovation Way
Greenfield, IN 46140
317.276.2000

May 11, 2015

Notifications Coordinator
U.S. EPA – OPP – RD
Document Processing Desk [NOTIF]
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

SUBJECT: Notification to replace production site listed on the Confidential Statement of Formula for Spinetoram 11.2% Cat [alternate brand name: Cheristin for cats] per PR Notice 98-10

COMPANY: Elanco Animal Health, A Division of Eli Lilly & Company
2500 Innovation Way
Greenfield, IN 46140

CONTACT: Casey Ash
Associate – Good Promotional Practices
Office: 317-277-4277
Fax: 317-651-6484
Email: ash_casey@elanco.com

PRODUCT: Spinetoram 11.2% Cat [EPA Registration No. 72642-10]

Dear Notifications Coordinator:

On behalf of Elanco Animal Health, I submit for your review and concurrence a notification to replace the production site listed on the Confidential Statement of Formula for Spinetoram 11.2% Cat.

This notification is permitted per PRN 98-10 based on the following conditions:

1. There has been no change in the formulation of Spinetoram 11.2% Cat
2. There has been no change in the identity or source of active ingredients

In addition to this letter, this submission includes:

- Fully executed application for pesticide registration [8570-1]
- Two original and signed CSFs per PRN 98-10 (VI)(5) [8570-4]

Should you have any questions or further information be required, please do not hesitate to contact me at (317) 277-4277 or ash_casey@elanco.com.

Sincerely,

Casey Ash
Associate – Good Promotional Practices
Elanco Animal Health



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 72642-10	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Spinetoram 11.2% Cat	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Elanco Animal Health, A Division of Eli Lilly & Company; 2500 Innovation Way; PO Box 708; Greenfield, IN 46140 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. N/A Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Replace production site listed on the confidential statement of formula.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container 6	If "Yes" Package wgt.	<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.026 fl oz		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Casey Ash	Title Associate	Telephone No. (Include Area Code) (317) 277-4277
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Casey Ash</i>	3. Title Associate - Good Promotional Practices	
4. Typed Name Casey Ash	5. Date May 11, 2015	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 23, 2015

Ms. Holly Settles
Research Scientist CMC Regulatory
Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140

Subject: Notification per PRN 98-10 – Change in Formulation Process
Product Name: Cheristin for Cats
EPA Registration Number: 72642-10
Application Date: April 16, 2015
Decision Number: 503589

Dear Ms. Settles:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The Notification of change in formulation process for this product is acceptable and has been placed in our records.

If you have any questions, you may contact Betty R. Williams at (703) 308-0132 or via email at williams.bettyr@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Walsh".

Michael Walsh
Product Manager 11
Invertebrate & Vertebrate Branch 2
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 72642-10	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Spinetoram 11.2% Cat [Alt Brand Name: Cheristin for Cats]	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) Elanco Animal Health, A Division of Eli Lilly and Company 2500 Innovation Way, PO Box 708 Greenfield, IN 46140 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This is a notification of a change in the description of the manufacturing process for Spinetoram 11.2% Cat.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted	If "Yes" Unit Packaging wgt. 0.026 fl z	No. per container See below	If "Yes" Package wgt	No. per container	<input type="checkbox"/> Plastic
					<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					<input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 1,2,3,4,6,8,12		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Holly Settles	Title Research Scientist - CMC	Telephone No. (Include Area Code) 317-276-4445
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Holly Settles</i>	3. Title Research Scientist - CMC Regulatory	
4. Typed Name Holly Settles	5. Date April 16, 2015	



Elanco Animal Health

2500 Innovation Way
Greenfield, IN 46140
317.276.2000

Notifications Coordinator
U.S. EPA – OPP – RD
Document Processing Desk [NOTIF]
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

April 16, 2015

SUBJECT: Notification to Change in Formulation Process

COMPANY: Elanco Animal Health, A Division of Eli Lilly & Company
2500 Innovation Way
Greenfield, IN 46140

CONTACT: Holly Settles
Research Scientist – CMC Regulatory
Office: 317-276-4445

PRODUCT: Spinetoram 11.2% Cat
(Alternate Brand Name: Cheristin for Cats)
[EPA File Symbol 72642-10]

Dear Notifications Coordinator:

On behalf of Elanco Animal Health, I submit for your review and concurrence a notification change to the Description of the Commercial Formulation Process.

This change is permitted per PRN 98-10 based on the following conditions:

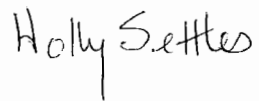
1. The product is made by a non-integrated system (there is no chemical reaction involved)
2. The certified limits of the active and inert ingredients do not change as a result of the change in the formulation process.
3. The physical/chemical/biological characteristics and/or the effectiveness of the product will not change.

In addition to this letter, this application contains:

- A fully executed application for pesticide registration [8570-1]
- A certification statement
- The currently approved Description of the Commercial Formulation Process
- The new Description of the Commercial Formulation Process

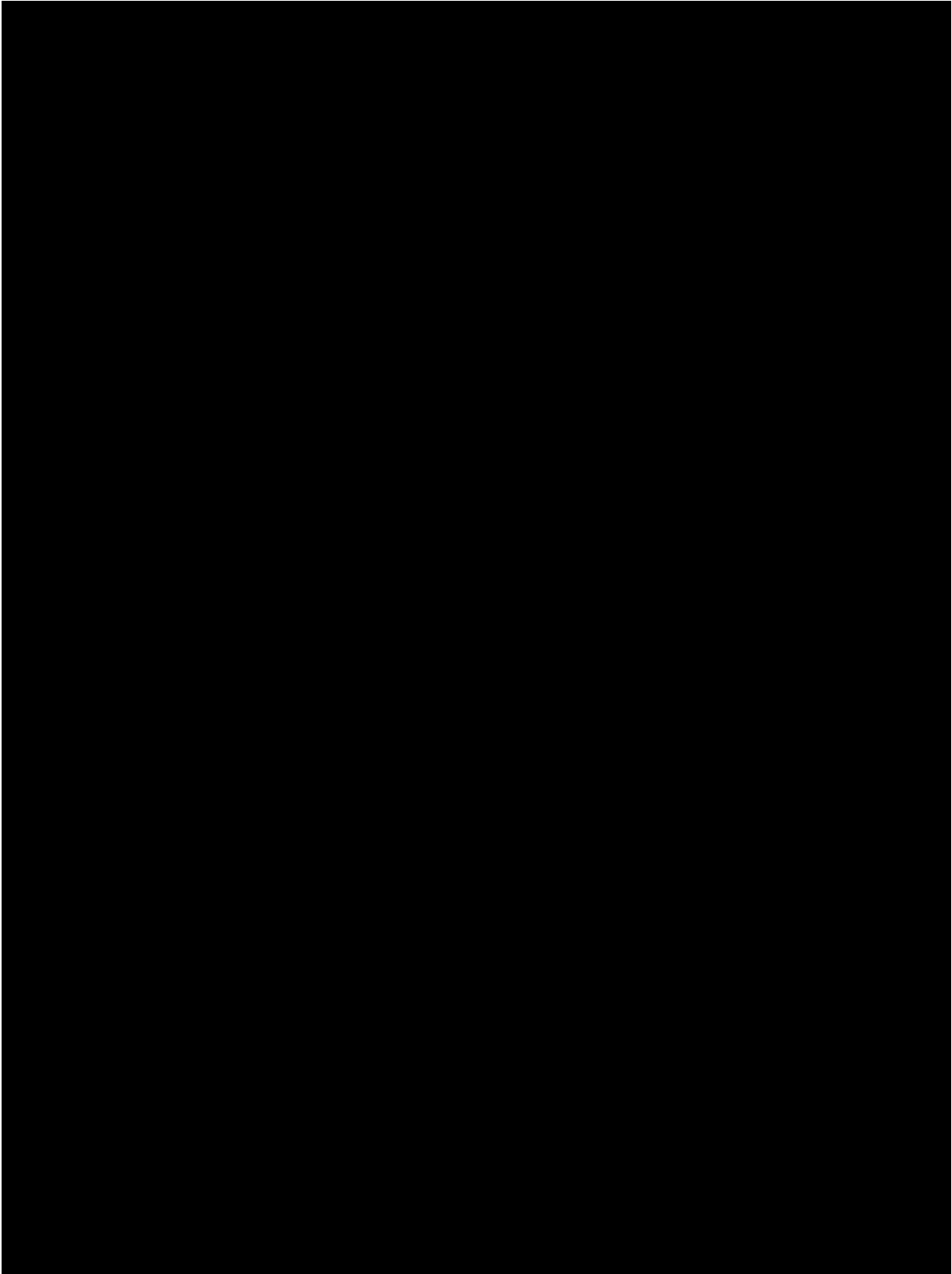
Should you have any questions or further information is required, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink that reads "Holly Settles". The script is cursive and fluid, with the first name "Holly" and last name "Settles" clearly distinguishable.

Holly Settles
Research Scientist CMC Regulatory
Elanco Animal Health

Currently Approved Process Description



Manufacturing process information may be entitled to confidential treatment



Elanco Animal Health

2500 Innovation Way
Greenfield, IN 46140
317.276.2000

RE: Notification of Change in Formulation Process [EPA Registration # 72642-10]

Explanation Continued:

“This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under section 12 and 14 of FIFRA.”

Signature Holly Settles Date 16 APR 2015
Holly Settles

Holly Settles
Elanco Animal Health
Research Scientist – CMC Regulatory
(317) 276-4445
settles_holly_a@elanco.com

Receipt for Section 3

S: 967220

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Notification

Fee For Service: ☐ Yes ☒ No

Company: 72642 ELANCO ANIMAL HEALTH



Risk Manager: Registration Division, Risk Management Team 11

Product #: 72642-10 Product Name: CHERISTIN FOR CATS

Override#:

Me Too

Me Too Product

Section3: 72642-9

Name: ASSURITY CAT

Application Date: 16-Apr-2015



OPP Rec'd Date: 17-Apr-2015



Front End Date: 17-Apr-2015



Risk Manager Send Date: 17-Apr-2015



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content	Des
Other	

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Notification of a change in the description of the manufacturing process

[Handwritten signature]

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

View/Edit

Sigam
13 (11)



Elanco Animal Health

2500 Innovation Way
Greenfield, IN 46140
317.276.2000

December 1st, 2014

Notifications Coordinator
U.S. EPA – OPP – RD
Document Processing Desk [NOTIF]
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202
Attn: Mark Suarez (PM-7)

49521700

SUBJECT: Submission of Storage Stability and Corrosion Characteristics Study per Conditional Approval

COMPANY: Elanco Animal Health, A Division of Eli Lilly and Company
2500 Innovation Way, Greenfield, IN 46140

CONTACT: Aaron E. Johnson
Principal Consultant – US Regulatory Innovation
Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140

PRODUCT: Cheristin for Cats [EPA Reg. No. 72642-10]

Dear Mr. Suarez,

Elanco Animal Health is submitting for your review ABC Study No. 80018: "Evaluation of Stability and Corrosion Characteristics of Cheristin". Elanco is providing this submission to fulfill the requirements for acceptable guideline studies for Storage Stability (OPPTS GLN: 830.6317) and Corrosion Characteristics (OPPTS GLN: 830.6320) as requested in the conditional approval letter for Cheristin. Following review of the attached study, Elanco Animal Health is requesting the issuance of a full approval.

If you have any questions or comments, please feel free to contact me at your earliest convenience. If I cannot be reached, please contact Cory Herr, Director of U.S. Regulatory Innovation, at (317) 651-2776 or at herr_cory_t@elanco.com.

Sincerely,

Aaron Johnson, DVM, MS
Elanco Animal Health
Office: 317-276-4021
Fax: 317-276-0614
Email: ajohnson@elanco.com

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter (Registrant):

EPA Company No. 72642

Elanco Animal Health
A Division of Eli Lilly and Company
2500 Innovation Way
Greenfield, Indiana 46140
Attn.: Aaron Johnson

2. Regulatory Action for which this package is submitted:

Submission of Storage Stability and Corrosion Characteristics Data to address conditional data requirements in Agency Stamped Accepted Label Approval, dated January 17, 2013, for Cheristin for Cats (EPA Reg. No. 72642-10).

3. Transmittal Date:

December 1, 2014


4. List of Submitted Documents:

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	GUIDELINE NUMBER
<u> </u>	ADMIN	<u>Administrative Materials</u> Cover Letter, Application form, Transmittal Document, Certification with Respect to Citation of Data, Data Matrix – confidential & sanitized versions	-----
49521701	1 of 1	Storage Stability and Corrosion Characteristics	OCSP 830.6317 & 830.6320

5. Company Contact:

Company Name: Elanco Animal Health

Company Representative:

 - Principal consultant

NAME AND TITLE

Tel: 317-276-0421
E-mail: ajohnson@elanco.com



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 17, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

ELANCO ANIMAL HEALTH
2500 INNOVATION WAY
PO.BOX : 708
GREENFIELD, IN 46140

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 04-DEC-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

49521701

* The following page(s) in this study is/are illegible due to the poor quality of the photocopying:
pp. 44-45, 53-55

Linda,

I have not replaced these pages as the ones provided are no better than the originals. I have changed the PRN 11-3 status of this study to "Pass" since not better copies are available.

Neresa
1/16

Receipt for Section 3			
S: 961272		Milestone Email:	
Regulatory Type:	Product Registration - Section 3	Resubmission:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Application Type:	Amendment	Fee For Service:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Company:	72642 ELANCO ANIMAL HEALTH	Billable:	<input type="radio"/> Yes <input checked="" type="radio"/> No
Risk Manager:		Registration Division, Risk Management Team 11	
Product #:	72642-10	Product Name:	CHERISTIN FOR CATS
Override#:			
Me Too Section3:	72642-9	Me Too Product Name:	ASSURITY CAT
Application Date:	01-Dec-2014	OPP Rec'd Date:	04-Dec-2014
Front End Date:	04-Dec-2014	Risk Manager Send Date:	04-Dec-2014
FFS Due Date:		Negotiated Due Date:	
OPP Target Date:			
Fast Track:	<input type="checkbox"/>	New Ingredient:	<input type="checkbox"/>
Receipt Description:		View/Edit	
storage stability & corrosion characteristics study per conditional approval		New Ingredient Request Date:	
		New Ingredient Received Date:	
Form A:	<input type="checkbox"/>	Signature Date:	
Form B:	<input type="checkbox"/>	Signature Date:	

Print Letter

Enter More Information

Tracking

Receipt Content	Des
Study	

Decision Seq: 498670 Action Code: 570, CONDITIONAL REGISTRATION FOLLOW-UP, DATA REQUIREMENT ...

FFS Start Date: Tentative Ind: No FQPA Clock:

Due Date: 24-Mar-2015 75-Day Due Date: Days Elapsed:

OPP Target Due Date: 21-Day Due Date: FFS Original Decision: ...

Negotiated Due Date: 45/90 Due Date:

Registrant: Predecisional Due Date: Add to Bundle? ☐

Response Due Date:

Current Status: PENDING (31-Dec-2014)

Bundle ID:

Decision Status

Tracking

Create Resubmission

FFS Letters

Waiver Documentation

Action Code History

Secondary Decision

Decision Bundle

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S:961272	Williams, Bettyr	72642-10	24-Mar-2015	PENDING

Storage Stability data (rejected).

Administrative Materials

Memorandum

Date: 12 / 18 / 14

To: PM 11, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☐ fully accepted submission
☐ partially accepted submission
☒ rejected submission

87459-1

ss/cc



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 72642-10	2. EPA Product Manager Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Cheristin for Cats	PM# 7	
5. Name and Address of Applicant (Include ZIP Code) Elanco Animal Health, A Division of Eli Lilly and Company 2500 Innovation Way, PO Box 708 Greenfield, IN 46140 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of storage stability and corrosion characteristics study as required as a condition of registration.

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. 0.026 fl oz	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt	2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper Other (Specify) _____
* Certification must be submitted	No. per container See below	No. per container	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container	4. Size(s) Retail Container 1,2,3,4,6,8,12	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other (Product Insert)	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Aaron E. Johnson	Title Principal Consultant	Telephone No. (Include Area Code) 317-276-1421	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			C. Date Application Received (Stamp)
2. Signature 	3. Title Principal Consultant - US Regulatory		
4. Typed Name Aaron E. Johnson	5. Date Dec 1, 2014		



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Elanco Animal Health, 2500 Innovation Way, Greentield, IN, 46140 Ph: 317-433-2167	EPA Registration Number/File Symbol 72642-10
Active Ingredient(s) and/or representative test compound(s) Spinetoram Technical (Spinetoram J & Spinetoram L)	Date December 1, 2014
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor Non-food Use	Product Name Cheristin for Cats

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

12/1/14

Typed or Printed Name and Title

Aaron Johnson - Principal Consultant, Reg Affairs

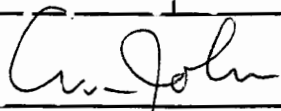


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 12/1/2014			EPA Reg No./File Symbol 72642-10		Page 1 of 2
Applicant's/Registrant's Name & Address Elanco Animal Health, 2500 Innovation Way, Greefield, IN, 46140 Ph: 317-433-2167			Product Cheristin for Cats		
Ingredient Spinetoram Technical (Spintoram J & Spinetoram L)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product identity and composition	48875801	Elanco Animal Health	Own	
830.1600	Description of starting materials used to make product	48875801	Elanco Animal Health	Own	
830.1650	Description of the formulation process	48875801	Elanco Animal Health	Own	
830.1670	Discussion of formation of impurities	48875801	Elanco Animal Health	Own	
830.1750	Certified Limits	48875801	Elanco Animal Health	Own	
830.1800	Enforcement Analytical Method	48875802	Elanco Animal Health	Own	
830.6000/7000	Physical/chemical characteristics	48875801	Elanco Animal Health	Own	
40 CFR 160.105	Test sample characterization & stability evaluation	48875805	Elanco Animal Health	Own	
40 CFR 160.105	Test sample characterization & stability evaluation	48875806	Elanco Animal Health	Own	
870.1100	Acute oral toxicity	47920101	Elanco Animal Health	Own	
870.1200	Acute dermal toxicity	47920102	Elanco Animal Health	Own	
870.1300	Acute inhalation toxicity	47920103	Elanco Animal Health	Own	
870.2400	Acute eye irritation	48875804	Elanco Animal Health	Own	
870.2500	Acute dermal irritation	47920104	Elanco Animal Health	Own	
870.2600	Skin Sensitization	47920105	Elanco Animal Health	Own	
Signature 			Name and Title Aaron Johnson - Principal Consultant/Regulatory Affairs		Date 12/01/2014





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
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			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
Signature 			Name and Title Aaron Johnson - Principal Consultant/Regulatory Affairs		Date 12/01/2014

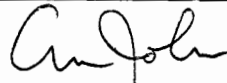


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Applicant's/Registrant's Name & Address Elanco Animal Health, 2500 Innovation Way, Greefield, IN, 46140 Ph: 317-433-2167			Product Cheristin for Cats		
Ingredient Spinetoram Technical (Spinetoram J & Spinetoram L)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7200	Companion Animal Safety (cats)	47899910	Elanco Animal Health	Own	
	Companion Animal Safety (kittens)	47899912	Elanco Animal Health	Own	
	Companion Animal Safety (kittens-excipients only)	48875805	Elanco Animal Health	Own	
	Bridging Rationale - Comp. Animal Safety/Toxicology	48875803	Elanco Animal Health	Own	
40 CFR 159.165	Adverse Incident Report related to 72642-9 (Assurity)	47899911	Elanco Animal Health	Own	
810.3300	Product Performance	48875806	Elanco Animal Health	Own	
	Product Performance	48875807	Elanco Animal Health	Own	
	Product Performance	48875808	Elanco Animal Health	Own	
830.6320	Storage Stability and Corrosion Characteristics	this submission	Elanco Animal Health	Own	
Signature 			Name and Title Aaron Johnson - Principal Consultant/Regulatory Affairs		Date 12/01/2014


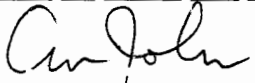


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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
Signature 			Name and Title Aaron Johnson - Principal Consultant/Regulatory Affairs		Date 12/01/2014



Elanco Animal Health

2500 Innovation Way
Greenfield, IN 46140
317.276.2000

May 22, 2014

U.S. Environmental Protection Agency
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

J

Attn: Mr. Mark Suarez, Project Manager

Subject: Submission of Revised Final Printed Labeling per PR Notice 98-10

Product: Cheristin™ for cats [EPA Reg. No. 72642-10]

Dear Mr. Suarez,

As instructed in the letter of issuance of the registration approval of this product, and due to requests made by the state of California, please find attached two copies of revised final product labeling for Chersitin™ for cats. The changes reflected in this revised labeling fall under a non-notification according to PR Notice 98-10.

Also, please be advised that the anticipated release date for this new final product labeling will be July 26, 2014.

A fully executed EPA Form 8570-1 is also attached to this letter.

If you have any questions or comments, please feel free to contact me at your earliest convenience. If I cannot be reached, please contact Cory Herr, Director of U.S. Regulatory Innovation, at (317) 651-2776 or at herr_cory_t@elanco.com.

Sincerely,

Aaron Johnson, DVM, MS
U.S. Regulatory Innovation
Elanco Animal Health
Office: 317-276-4021
Fax: 317-276-0614
Email: ajohnson@elanco.com

Attachments: Two copies of finished product labeling for Cheristin for Cats
Fully executed EPA Form 8570-1



United States
Environmental Protection Agency
Washington, DC 20460

Registration
Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 72642-10	2. EPA Product Manager Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Elanco Animal Health/Cheristin for Cats	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Elanco Animal Health, A Division of Eli Lilly and Co. 2500 Innovation Way, P.O. Box 708, Greenfield, IN 46140 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated Jan. 17, 2013
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Revised final printed labels with changes as requested by the state of California.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Aaron Johnson	Title Regulatory Consultant	Telephone No. (Include Area Code) 317-276-0421
-----------------------	--------------------------------	---

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature 	3. Title Regulatory Consultant
4. Typed Name Aaron Johnson	5. Date May 22, 2014

Elanco

Cheristin[™] for cats

Cheristin[™] for cats

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

More detailed directions for use are included in the box. Read the entire label, directions for use and frequency of application each time before using this product.

For prevention and treatment of fleas, part the hair on the neck at the base of the head and apply the contents of the applicator tube to a single spot on the skin of the cat. Do not apply on the surface of the cat's hair coat. Place the empty applicator tube in the trash.

Monthly application is recommended to prevent and treat flea infestations. Cheristin for cats starts working in 30 minutes and continues killing fleas for a full month after application.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

HAZARDS TO HUMANS: Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS: FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

SIDE EFFECTS: Monitor your cat after application. Side

effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetence have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

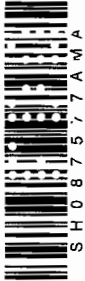
EPA Reg. No. 72642-10

EPA Est. No. 68669-NC-001

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CA4590

SH087577AMA



SH087577AMA

Cheristin[™] for cats

Elanco



7 27804 33385 0

Cheristin[™] for cats

Elanco

Elanco

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS
READ ALL DIRECTIONS BEFORE USING THIS PRODUCT
CONTENTS 6 - 0.026 fl oz (0.77 ml) applicator
TOTAL 100.0%
OTHER INGREDIENTS 88.8%
ACTIVE INGREDIENT Spinetoram (CAS# 187166-40-1 & 187166-15-0) 11.2%

ONLY FOR CATS AND KITTENS
EIGHT WEEKS OF AGE AND OLDER

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE
PREVENTION AND TREATMENT OF FLEA INFESTATIONS
spinetoram

Cheristin[™] for cats

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated 1-17-13



KEEP OUT
OF REACH
OF CHILDREN
CAUTION

TOPICAL APPLICATION

ONCE-A-MONTH

FAST ACTING - STARTS
KILLING FLEAS IN 30 MIN.

TOPICAL APPLICATOR 6

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

Cheristin[™] for cats
Elanco
TOPICAL APPLICATOR 6



Cheristin™
for cats Elanco.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

More detailed directions for use are included in the box. Read the entire label, directions for use and frequency of application each time before using this product.

For prevention and treatment of fleas, part the hair on the neck at the base of the head and apply the contents of the applicator tube to a single spot on the skin of the cat. Do not apply on the surface of the cat's hair coat. Place the empty applicator tube in the trash.

Monthly application is recommended to prevent and treat flea infestations. Cheristin for cats starts working in 30 minutes and continues killing fleas for a full month after application.

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

HAZARDS TO HUMANS:
Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

HAZARDS TO DOMESTIC ANIMALS: FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS: Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetence have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

CA4590
SH087305AMA

Manufactured for
Elanco Animal Health
A Division of
Eli Lilly and Company
Indianapolis, IN 46285

Cheristin™
for cats
Elanco.

Cheristin™
for cats Elanco.

EPA Reg. No. 72642-10
EPA Est. No. 68669-NC-001

Elanco and Cheristin are trademarks owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS
READ ALL DIRECTIONS BEFORE USING THIS PRODUCT
CONTENTS 1 - 0.026 fl oz (0.77 ml) applicator
Elanco.

ACTIVE INGREDIENT
Spinetoram (CAS# 187166-40-1 & 187166-15-0).....11.2%
OTHER INGREDIENTS.....88.8%
TOTAL.....100.0%

CAUTION
KEEP OUT OF
REACH OF
CHILDREN

TOPICAL APPLICATION

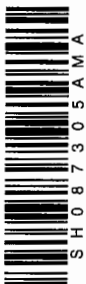
ONCE-A-MONTH

FAST ACTING - STARTS
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ONLY FOR CATS AND KITTENS
EIGHT WEEKS OF AGE AND OLDER
A ONCE-A-MONTH TOPICAL SOLUTION FOR THE
PREVENTION AND TREATMENT OF FLEA INFESTATIONS

spinetoram
for cats
Cheristin™

TOPICAL
APPLICATOR



SH087305AMA



Cheristin™ for cats spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION
FOR THE PREVENTION AND TREATMENT
OF FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS
EIGHT WEEKS OF AGE AND OLDER

ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 &
187166-15-0].....11.2%

OTHER INGREDIENTS.....88.8%
TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC
ANIMALS – CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetence have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.



2. Remove one applicator tube from the blister package.
3. Hold applicator tube in an upright position.
4. Press cap down until it clicks (indicating the tube has been punctured). Hold upright and remove cap. Check to be sure there is an opening at the tip of tube.
5. Part the hair on the neck at the base of the head until the skin is visible. Place the tip of the tube directly above the skin and squeeze the tube 2-4 times to expel the contents of the tube directly on the skin. For best results, apply at the base of the head, not between shoulder blades. Avoid getting the product in your pet's eyes or mouth. Treatment at the base of the head will minimize the opportunity for the cat to directly lick the product. Do not allow your cat to ingest this product. (There may be a small residual remaining in the tube after a full dose is expelled.)
6. Discard empty applicator tube in the trash.



Monthly application is recommended to prevent and treat flea infestations. Cheristin for cats starts working in 30 minutes and continues killing fleas for a full month after application.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage:

Store in original package in a cool dry place.

Pesticide Disposal:

Call your local solid waste agency or 1-800-CLEANUP or equivalent organization for disposal instructions. Unless otherwise instructed place in trash. Never pour unused product down the drain or on the ground.

Container Handling:

If empty: Non-refillable container. Do not reuse this container. Place in the trash, or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Read the entire label, directions for use and frequency of application each time before using this product. For external use on cats and kittens only.

FREQUENCY OF APPLICATION

To kill fleas and prevent reinfestations, apply to cats and kittens 8 weeks of age and older as follows:

HOW TO APPLY

1. Use only on cats and kittens 8 weeks of age and older and weighing 1.8 lbs or more. Do not use more than a single dose on cats weighing greater than 20 lbs.

LIMITED WARRANTY AND LIMITATIONS OF LIABILITY

By using, buying or handling this product, users or buyers accept the following conditions, disclaimer of warranties and limitations of liability. The directions for use of this product are believed to be adequate and must be followed carefully. All risks of product use or handling are assumed by the user or buyer. No agent of Elanco is authorized to make, extend or modify any warranties. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW ELANCO MAKES NO OTHER WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. ELANCO DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. To the extent consistent with applicable law the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, is limited to the purchase price paid or replacement of the product.

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-10
EPA Est. No. 68669-NC-001

Cheristin is a trademark owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.

CA4590

PA087305AMX

Cheristin™
for cats
spinetoram 11.2%
Only for Cats and Kittens
8 weeks of age and older
0.026 fl oz
EPA Reg. No 72642-10
CAUTION
Keep Out of Reach of Children
Read Entire Label Before Use

CA4590 **Elanco™** 79906
FL086371AMB Lot No.

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Elanco™

CA4590

79905
FL086371AMA

Lot No.



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21	22	23	24	25	26	27
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Place stickers on your calendar as a reminder to apply Cheristin for cats only to cats and kittens 8 weeks of age and older.

Visit www.CheristinForCats.com to sign up and receive an email reminder from your cat

when it is time to receive Cheristin for cats.

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EP086371AMB

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CA4590
EP086371AMA



79909

Cheristin[®]
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spinetoram 11.2%
Cats and Kittens
8 weeks & older
EPA Reg. No.
72642-10
 **Elanco[™]** CA4590
CAUTION
Keep Out of
Reach of Children
Read Entire Label
Before Use
0.026 fl oz
EP087423AMX

Elanco.

Cheristin™
for cats

Cheristin™ for cats

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

More detailed directions for use are included in the box. Read the entire label, directions for use and frequency of application each time before using this product.

For prevention and treatment of fleas, part the hair on the neck at the base of the head and apply the contents of the applicator tube to a single spot on the skin of the cat. Do not apply on the surface of the cat's hair coat. Place the empty applicator tube in the trash.

Monthly application is recommended to prevent and treat flea infestations. Cheristin for cats starts working in 30 minutes and continues killing fleas for a full month after application.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

HAZARDS TO HUMANS: Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS: FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

SIDE EFFECTS: Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetence have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

EPA Reg. No. 72642-10
EPA Est. No. 68669-NC-001

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CA4590



SH087577AMA

Cheristin™
for cats

Elanco.



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Cheristin™
for cats

Elanco.

Elanco.

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS
READ ALL DIRECTIONS BEFORE USING THIS PRODUCT
CONTENTS 6 - 0.026 fl oz (0.77 ml) applicator
TOTAL 100.0%
OTHER INGREDIENTS 88.8%
Spinetoram (CAS# 187166-40-1 & 187166-15-0)...11.2%
ACTIVE INGREDIENT

ONLY FOR CATS AND KITTENS
EIGHT WEEKS OF AGE AND OLDER

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE
PREVENTION AND TREATMENT OF FLEA INFESTATIONS

spinetoram
for cats

Cheristin™

TOPICAL
APPLICATOR
6

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

KEEP OUT
OF REACH
OF CHILDREN
CAUTION

TOPICAL APPLICATION

ONCE-A-MONTH

FAST ACTING - STARTS
KILLING FLEAS IN 30 MIN.



Cheristin™
for cats

Elanco.

TOPICAL
APPLICATOR





Cheristin™
for cats **Elanco.**

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For prevention and treatment of fleas, part the hair on the neck at the base of the head and apply the contents of the applicator tube to a single spot on the skin of the cat. Do not apply on the surface of the cat's hair coat. Place the empty applicator tube in the trash.

Monthly application is recommended to prevent and treat flea infestations. Cheristin for cats starts working in 30 minutes and continues killing fleas for a full month after application.

**PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND
DOMESTIC ANIMALS - CAUTION**

HAZARDS TO HUMANS:
Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

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HAZARDS TO DOMESTIC ANIMALS: FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS: Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetence have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

CA4590
SH087305AMA

Manufactured for
Elanco Animal Health
A Division of
Eli Lilly and Company
Indianapolis, IN 46285

Cheristin™
for cats **Elanco.**

Cheristin™
for cats **Elanco.**

EPA Reg. No. 72642-10
EPA Est. No. 68669-NC-001

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**SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS
READ ALL DIRECTIONS BEFORE USING THIS PRODUCT**

ACTIVE INGREDIENT
Spinetoram (CAS# 187166-40-1 & 187166-15-0) 11.2%
OTHER INGREDIENTS 88.8%
TOTAL 100.0%

ONLY FOR CATS AND KITTENS
EIGHT WEEKS OF AGE AND OLDER
A ONCE-A-MONTH TOPICAL SOLUTION FOR THE
PREVENTION AND TREATMENT OF FLEA INFESTATIONS

Cheristin™
for cats
spinetoram

TOPICAL
APPLICATOR



FAST ACTING - STARTS
KILLING FLEAS IN 30 MIN.

ONCE-A-MONTH

TOPICAL APPLICATION

KEEP OUT OF
REACH OF
CHILDREN
CAUTION



SH087305AMA



Cheristin™ for cats spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION
FOR THE PREVENTION AND TREATMENT
OF FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS
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ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 &
187166-15-0].....11.2%

OTHER INGREDIENTS.....88.8%
TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC
ANIMALS – CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.



2. Remove one applicator tube from the blister package.
3. Hold applicator tube in an upright position.
4. Press cap down until it clicks (indicating the tube has been punctured). Hold upright and remove cap. Check to be sure there is an opening at the tip of tube.
5. Part the hair on the neck at the base of the head until the skin is visible. Place the tip of the tube directly above the skin and squeeze the tube 2-4 times to expel the contents of the tube directly on the skin. For best results, apply at the base of the head, not between shoulder blades. Avoid getting the product in your pet's eyes or mouth. Treatment at the base of the head will minimize the opportunity for the cat to directly lick the product. Do not allow your cat to ingest this product. (There may be a small residual remaining in the tube after a full dose is expelled.)
6. Discard empty applicator tube in the trash.



Monthly application is recommended to prevent and treat flea infestations. Cheristin for cats starts working in 30 minutes and continues killing fleas for a full month after application.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage:

Store in original package in a cool dry place.

Pesticide Disposal:

Call your local solid waste agency or 1-800-CLEANUP or equivalent organization for disposal instructions. Unless otherwise instructed place in trash. Never pour unused product down the drain or on the ground.

Container Handling:

If empty: Non-refillable container. Do not reuse this container. Place in the trash, or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

FIRST AID

IF IN EYES:

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DIRECTIONS FOR USE:

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Read the entire label, directions for use and frequency of application each time before using this product. For external use on cats and kittens only.

FREQUENCY OF APPLICATION

To kill fleas and prevent reinfestations, apply to cats and kittens 8 weeks of age and older as follows:

HOW TO APPLY

1. Use only on cats and kittens 8 weeks of age and older and weighing 1.8 lbs or more. Do not use more than a single dose on cats weighing greater than 20 lbs.

LIMITED WARRANTY AND LIMITATIONS OF LIABILITY

By using, buying or handling this product, users or buyers accept the following conditions, disclaimer of warranties and limitations of liability. The directions for use of this product are believed to be adequate and must be followed carefully. All risks of product use or handling are assumed by the user or buyer. No agent of Elanco is authorized to make, extend or modify any warranties. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW ELANCO MAKES NO OTHER WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. ELANCO DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. To the extent consistent with applicable law the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, is limited to the purchase price paid or replacement of the product.

Manufactured for
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A Division of Eli Lilly and Company
Indianapolis, IN 46285

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EPA Est. No. 68669-NC-001

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CA4590

PA007305AMX

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spinetoram 11.2%
Only for Cats and Kittens
8 weeks of age and older
0.026 fl oz
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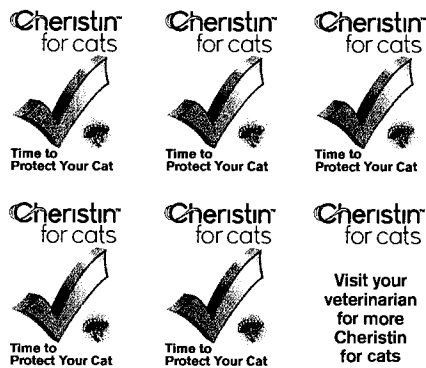
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Elanco™

CA4590

79905
FL086371AMA

Lot No.



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EP086371AMB

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CA4580
EP066371A1



79909

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Cats and Kittens
8 weeks & older
EPA Reg. No.
72642-10

 **Elanco[™]** CA4590
CAUTION
Keep Out of
Reach of Children
Read Entire Label
Before Use
0.026 fl oz
EP087423APX

FOR OFFICIAL USE ONLY

FILE SYMBOL

REGISTRATION NO.

72642-RN

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER
JUN 29 2012		

**Do Not Write Comments,
Formula, or Parts of Formula
on This Envelope**

NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

